

COLD FLU AND SORE THROAT RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled FOODHOLD U.S.A., LLC

COLD, FLU & SORE THROAT RELIEF

Drug Facts

Active Ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves:
 - nasal congestion
 - headache
 - cough
 - minor aches and pains
 - sore throat
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 softgels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

When using this product, do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see Overdose warning)**
- do not take more than 12 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

Other information

- store between 20-25°C (68-77°F)
- avoid excessive heat

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

Questions or Comments?

Call: 1-855-215-8180

PRINCIPAL DISPLAY PANEL - Carton Label

CAREONE COLD, FLU & SORE THROAT RELIEF 16 SOFTGELS

NDC 41520-984-14

*Compare to the active ingredients in Mucinex[®] Fast-Max[®] Cold, Flu & Sore Throat

CAREone®

COLD, FLU & SORE THROAT RELIEF

Pain Reliever/Fever Reducer - Acetaminophen • Cough Suppressant - Dextromethorphan HBr
Expectorant - Guaifenesin • Nasal Decongestant - Phenylephrine HCl

NDC 41520-00250-14

CAREone®

Compare to the Active
Ingredients in Mucinex®
Fast-Max® Cold, Flu
& Sore Throat**

THIS PRODUCT IS PACKAGED
IN A CHILD RESISTANT AND
TAMPER EVIDENT PACKAGE.
USE ONLY IF BLISTERS ARE
INTACT

**COLD, FLU & SORE
THROAT RELIEF**

Pain Reliever/Fever Reducer - Acetaminophen
Cough Suppressant - Dextromethorphan HBr
Expectorant - Guaifenesin
Nasal Decongestant - Phenylephrine HCl

MAXIMUM STRENGTH*
RELIEVES HEADACHE & FEVER
CONTROLS COUGH
THINS & LOOSENS MUCUS
RELIEVES NASAL CONGESTION
NON-DROWSY, FOR AGES 12 +

Actual Size



**16
SOFTGELS**

*Per 4000 mg dose
Do not take more than
4 total of 16 softgels
in a 24-hour period



PARENTS:

Learn about teen medicine at

www.StopMedicineForTeens.org



5-TAB
0913



LOT NO:
EXP DATE

COATING
FREE AREA

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts	Drug Facts (continued)
<p>Active Ingredients (in each softgel)</p> <p>Acetaminophen 325 mg _____ Pain reliever/fever reducer Dextromethorphan HBr 10 mg _____ Cough suppressant Guaifenesin 200 mg _____ Expectorant Phenylephrine HCl 5 mg _____ Nasal decongestant</p> <p>Purposes</p> <p>temporarily relieves these common cold and flu symptoms: nasal congestion headache cough sore throat temporarily reduces fever helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of built-up mucus and make coughs more productive</p> <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 12 liquid gels in 24 hours, which is the maximum daily amount with other drugs containing acetaminophen 3 or more alcoholic drinks daily while using this product</p> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin redness hives rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.</p> <p>Do not use</p> <p>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.</p> <p>Ask a doctor before use if you have</p> <p>liver disease heart disease diabetes high blood pressure thyroid disease</p>	<p>trouble urinating due to an enlarged prostate gland persistent or chronic cough such as occurs with emphysema, asthma, chronic bronchitis, or emphysema cough that occurs with too much phlegm (mucus)</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p> <p>When using this product do not use more than directed.</p> <p>Stop use and ask a doctor if</p> <p>irritation, dizziness, or drowsiness occur pain, nasal congestion, or cough gets worse or lasts more than 7 days fever gets worse or lasts more than 3 days redness or swelling is present new symptoms occur cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Directions</p> <p>do not take more than directed (see Overdose warning) do not take more than 12 liquid gels in any 24-hour period adults and children 12 years of age and older: take 2 liquid gels every 4 hours children under 12 years of age: do not use</p> <p>Other information</p> <p>store between 20-25°C (68-77°F) avoid excessive heat</p> <p>Inactive ingredients</p> <p>FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white ink</p> <p>Questions or Comments? Call: 1-855-415-4146</p> <p>DISTRIBUTED BY FOODHOLD U.S.A., LLC LANDOVER, MD 20735 • 1-877-466-9949 852018 S&S Strands, LLC MADE IN CHINA Quality guaranteed or your money back.</p>

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AH03-01

COLD FLU AND SORE THROAT RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-984
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange (clear)	Score	no score
Shape	CAPSULE (oblong)	Size	26mm
Flavor		Imprint Code	PC26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-984-14	2 in 1 CARTON	10/05/2016	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/05/2016	

Labeler - FOODHOLD U.S.A., LLC (809183973)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(41520-984)

Revised: 11/2024

FOODHOLD U.S.A., LLC